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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,086	10/30/2003	Ronald H.P. Brus	2578-6158US	9184

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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,086	BRUS ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,10,12 and 14-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,10,12 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-24 are pending in the application. In the prior action, the Final Action mailed on December 14, 2005, claims 1-24 were pending, with claims 1-7, 10, and 12-16 under consideration and rejected; and claims 8, 9, 11, and 17-24 withdrawn as being drawn to a nonelected inventions. In the After Final response of March 14, 2006, the Applicant amended claims 1 and 12, and cancelled claims 2-6, 8, 9, 11, 13, and 17-24.

2. Claims 1, 7, 10, 2, and 14-16 are pending and under consideration.

3. In view of the new rejections presented below, the Finality of the prior action is withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **(Prior Rejection- Withdrawn)** Claims 1-7, 10, and 12-16 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for methods for the identification of compounds with antiviral activity against any virus "other than an adenovirus." In view of the Applicant's arguments in traversal, which are found persuasive, the rejection is withdrawn.

6. **(Prior Rejection- Withdrawn)** Claims 1-7, 10, and 12-16 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of determining if a compound interferes with a virus's life cycle comprising the use of a cell transformed with an adenovirus type 5 E1 protein, does not reasonably provide enablement for methods involving the transformation of any cell with any adenoviral E1 gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. In view of the amendments to the claims, limiting them to the use of PER.C6 cells, the rejection is withdrawn.

7. **(New Rejection)** Claims 1, 7, 10, 12, and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The PER.C6 cells are required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit. See 37 CFR 1.802. One cannot practice the claimed invention without the PER.C6 cells. Therefore, access to the cells is required to practice the invention.

It is noted that the Applicant has submitted papers indicating that the PER.C6 cells have been deposited in accordance with the Budapest treaty, and that any restrictions on access to the cells will be removed upon grant of a patent on this application. See, Declaration of Ronald Brus, filed March 14, 2006.

However, in addition to these requirements, the Applicant is also required to include in the application the identifying information set forth in 37 CFR 1.809(d). Because the Application does not include the full name, address, and date of deposit in the application, all of the deposit conditions have not yet been met.

It is suggested that this additional information be added to the identification of the deposit on page 11 (paragraph [0044]) of the application.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. **(Prior Rejections- Withdrawn)** Claims 1-7, 10, 12, 13, and 16 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Burk et al. (WO 91/15573- of record in the October 2003 IDS) in view of Hateboer et al. (WO 00/63403- of record in the October 2003 IDS). Claims 1-7, 10, 12-14, and16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Burk and Hateboer as applied to claims 1-3, 5-7, 12, 13, and 16 above, and further in view of Lin et al. (J Virol Methods 88: 219-25). Claims 1-7, and 12-16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Burk and Hateboer as applied to claims 1-3, 5-7, 12, 13, and 16 above, and further in view of Halliday et al. (WO 99/51776- of record in the October 2003 IDS). In view of the amendments to the claims, limiting them to the use of PER.C6 cells, the rejections are withdrawn.

10. **(New Rejection)** Claims 1, 7, 10, 12, and 16 are rejected under 35 U.S.C. 103(a) as being obvious over Burk et al. (WO 91/15573- of record in the October 2003 IDS) in view of either of the Pau et al. references U.S. 2006/0051747 or U.S. 2006/0063261. These claims read on methods of determining whether a compound has influences a phase in a viral life cycle comprising the steps of providing a PER.C6 cell with at least the viral elements required for the indicated phase (but may include the whole virus), providing the compound to be tested, and determining whether the compound influences the phase of the viral life cycle.

As has been previously described, Burk teaches the making and use of an immortalized human cell for the production of viruses, particularly Hepatitis virus, and viral proteins. Pages 3-4. The reference also teaches that the cells may be used in assays for the identification of compounds that inhibit the growth of virus that can infect the cells. Page 4. Thus, the reference teaches the use of such cells for the identification of compounds that can influence a phase in a viral life cycle. The reference also teaches the immortalization of the cells to be used. Further, the reference also teaches that the methods of identifying anti-viral compounds may include infection of the immortalized cells with whole virus, and then screening for a viral activity, such as its growth. Page 27, lines 16-25. However, while the reference teaches that such immortalization may be performed through the incorporation of virus derived genes into the cells, it does not teach or suggest the use of the PER.C6 cell.

Each of the Pau references teaches the use of the immortalized PER.C6 cells for viral replication, including for the replication and production of Hepatitis viruses. See e.g., page 5 of either Pau reference. The references also teach that these cells demonstrate additional advantages over the use of other cell types. U.S. 2006/0051747, page 5 paragraph [0074]; and U.S. 2006/0063261, page 5 paragraph [0077]. Further, the reference demonstrates that the PER.C6 cells are capable of replicating a number of different non-adenoviruses. Thus, based on the teachings of these references, those in the art would both be motivated to use, and would have had a reasonable expectation of success in the use of, PER.C6 cells for performing the methods of Burk. The combination of Burk with either of the Pau references therefore renders the claimed invention obvious.

The applied Pau references have a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

11. **(New Rejection)** Claims 1-7, 12, and 14-16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Burk in view of either of the Pau et al. references as applied to claims 1, 7, 10, 12, and 16 above, and further in view of Halliday et al. (WO 99/51776- of record in the October 2003 IDS). Claim 14 further requires that the compound to be tested is compound from a library. Claims 15 is directed to high-throughput methods of identifying anti-viral compounds using the method of claim 1. The teachings of the Burk and Pau references have been descried above. While the teachings of Burk and Pau teach the method of claim 1, the references do no teach that the method would be suitable for high-throughput screening. However, the Halliday et

al. reference teaches a high-throughput method of identifying anti-viral compounds comprising a substantially similar method to that suggested by Burk and Pau. See e.g., Halliday, claim 1, and pages 5-6. Because the reference teaches that such high-throughput methods are useful for the screening of large numbers of compounds (page 1), it would have been obvious to those in the art to adapt the methods of Burk and Pau such that they could be used as high-throughput methods as suggested by Pau. The combination of these references therefore renders the claimed inventions obvious.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

James C. Housel 4/28/06
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